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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,464	05/03/2007	Marsha A. Moses	CMC-011	5882

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GOODWIN PROCTER LLP
PATENT ADMINISTRATOR
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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

NOTIFICATION DATE	DELIVERY MODE
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10/07/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/585,464	Applicant(s) MOSES ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>July 7, 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group (claims 1-16) in the reply filed on July 2, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-19 are pending.
Claims 17-19, drawn to non-elected inventions are withdrawn from examination.
Claims 1-16 were examined on the merits.

Claim Objections

3. Claim 3 is objected to because of the following informality: there is no period at the end of the text, hence it is not clear if the claim is missing additional language.
Correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 4, 5 and 7-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Iba et al. (Am J. Pathol. 154(5):1489-501, May 1999). Iba discloses “[t]he distribution of ADAM 12 in... 37 human carcinomas compared with the normal counterpart tissue... investigated by immunohistochemistry”, see page 1493, Results section. These tissue specimens are from human carcinomas comprising ductal breast carcinoma, adenocarcinoma of the colon and rectum, squamous cell carcinoma of the lung and adenocarcinoma of the stomach, see page 1490, Tissue samples...section. Adjacent nontumorous tissues were also investigated. “All 15 cases of breast carcinomas exhibited intense ADAM 12 immunoreactivity (Figure 1A) using several different antibodies, whereas in normal breast tissue, only a few scattered luminal cells of the ducts exhibited ADAM 12 immunoreactivity (Figure 1E)”, see page 1493, Results section. Labeled monoclonal antibodies to human ADAM 12 were implemented in the immunohistochemistry assays, see page 1490, Antibodies and Immunohistochemistry...sections; and Figure 1 on page 1494.

Normal and cancerous human breast tissue specimens were analyzed by RT-PCR using specific primers for ADAM 12-L and ADAM 12-S, see last sentence of column 1, page 1493; and Figure 1 on page 1494. “Breast carcinoma tissue appeared to contain

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more ADAM 12-L transcript than normal breast tissue (Figure 1G)", see bridging sentence of columns 1 and 2 on page 1493.

6. Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2003/0148410 A1 (filed November 21, 2002). The publication discloses methods for detecting and characterizing human colon cancers implementing assays determining the level of mRNA marker or marker protein, see abstract; and sections 0276-0299 beginning on page 31. Table 1 lists all of the markers disclosed in the invention including ADAM 12, art known as a disintegrin and metalloproteinase domain 12 or meltrin alpha, see page 4, section 0060 and the table. The ADAM 12 marker can be detected blood fluids, stool, colon lavage fluids, lymph fluids and urine via an antibody which is labeled by several means, see page 3, section 0048; page 10, section 0114; and page 33, section 0300.

7. Claims 1, 2, 4, 5 and 7-16 are rejected under 35 U.S.C. 102(a) as being anticipated by Le Pabic et al. (Hepatology 37: 1056-1066, published December 2003). Le Pabic discloses a method of detecting steady-state of ADAM12 mRNA levels and mRNA expression in liver tissue samples including hepatocellular carcinomas, liver metastases from colorectal cancers, focal nodular hyperplasia and nontumoral livers, see abstract; page 1057, Tissue Samples section; page 1058, Immunohistochemistry section; Figure 1 on page 1059; page 1062, ADAM9 and ADAM12...section and Figure 5; and Figure 6 on page 1063.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iba et al. (Am J. Pathol. 154(5):1489-501, May 1999), and further in view of U.S. Patent Application Publication number 2003/0148410 A1 (filed November 21, 2002). The teachings of Iba have been presented in the preceding 102(b) rejection. Iba does not teach the disclosed method, wherein a biological sample assayed for ADAM 12 is urine.

However, the publication teaches urine as a biological sample to test for the present or absence of ADAM 12. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of both documents assay a plethora of biological samples for ADAM 12, particularly a urine sample. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings because the publication implemented the diagnostic assay using urine as a test sample and ADAM 12 is clearly and definitively associated with tumor cancer, see publication, page 1, section 0008 and page 33, section 0300; and Iba, abstract.

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10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
29 September 2008
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643